

## REMARKS

Claims 3, 4, and 56 are currently pending in the present application, and have been amended herein. Claims 1, 2, 5-55, and 57-63 were previously withdrawn as being directed to a non-elected invention.

### Telephone Interview

Applicants thank the Examiner for the courtesy shown their representatives, Dr. Kathryn Doyle and Gail Griffin, during the telephone interview of February 5, 2003. During that interview, the Examiner's outstanding rejections of the claims, as well as the scope of allowable subject matter, were discussed. It is Applicants' understanding that, according to the Examiner, claims amended to reflect a rat having an FST score lower than 8 may be allowable, provided that a Declaration from an inventor is filed stating that the claimed rat having this FST score does not exist in nature.

Based on the telephonic interview with the Examiner, Applicants submit herewith a Declaration pursuant to 37 C.F.R. § 1.132 describing results obtained by Dr. Eva Redei, a co-inventor of the present claims. As described in greater detail below, Applicants respectfully submit that the Declaration of Dr. Eva Redei pursuant to 37 C.F.R. § 1.132 being submitted herewith, in conjunction with the claim amendments made herein, overcomes the Examiner's rejections as set forth in the Final Office Action and places the claims in condition for allowance.

### Rejection of claims 3 and 4 in view of 35 U.S.C. §101

Claims 3 and 4 have been rejected by the Examiner as being non-statutory subject matter because, in the Examiner's view, the claimed WLI rat is apparently indistinguishable from a product of nature. Applicants respectfully traverse this rejection.

Applicants have amended claim 3 herein to recite that the claimed WLI rat has an FST score of less than about 6. A rat with an FST score of less than about 6 does not exist in nature and, therefore, is indeed patentable subject matter. Support for this amendment can be found on page 12 of the specification, from line 13 to line 20. Further, beginning at line 28 on page 12 of the specification, Applicants describe that the WLI substrain of rats does not exist in nature. The individual rats of the WLI substrain,

particularly those rats in the F2 generation and higher, exhibit very similar behavioral phenotypes, which are distinctly different from the parental strain.

The careful selective mating by the inventors of two parental F1 generation WKY rats having a specific FST score makes the production of F2 and higher generations non-random and reproducible. Additional data presented in the Declaration of Dr. Eva Redei (submitted herewith) demonstrates the reproducibility of obtaining WLI rats having FST scores of less than 6 in F2 and higher generations. Specifically, Dr. Redei's Declaration shows that it is possible to obtain, using the procedures described in the present application, a WLI rat of an F9 generation having an FST score of  $4.2 \pm 0.6$ , and a WLI rat of an F10 generation having an FST score of  $5.0 \pm 0.6$ . These data further demonstrate that a WLI rat of the present invention has an FST score of "less than about 6." Importantly, Dr. Redei's Declaration states that a rat of the presently-claimed invention does not exist in nature.

Additionally, Applicants have amended claim 4 herein to recite that the claimed WLI rat has an FST score of "less than about 4." Support for this amendment can be found in the specification on page 41, at lines 21-22.

Therefore, the WLI rat claimed in the instant invention is indeed distinguishable from a product of nature, because the selective mating of rats of the F1 generation is not random, and because WLI rats having an FST score of less than about 6 do not exist in nature. Applicants have directed the Examiner's attention to support for the amendments to claims 3 and 4 in the specification and, therefore, these amendments do not add new matter. For these reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

#### Rejection of claims 3 and 4 in view of 35 U.S.C. §102(b)

The Examiner has rejected claims 3 and 4 as being anticipated by Paré, et al. (1997, Physiol & Behav, 62(3):643-648). In the Examiner's view, Paré et al. teach rats having phenotypes (i.e., FST scores of about 8 or less) overlapping with rats claimed in claims 3 and 4. Further, the Examiner states that the patentability of a "product-by-process" claim is determined by the novelty of the claimed product itself, and it is the Examiner's view that Applicants' claims do not recite a novel product. Applicants respectfully disagree with the Examiner's analysis for the following reasons.

It is hornbook law that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added)). Therefore, Paré must describe each and every element of the claims in order to anticipate these claims under 35 U.S.C. § 102.

Applicants have amended claim 3 such that the claim is now drawn to a rat having an FST score of less than about 6. Applicants have amended claim 4 to recite a rat having an FST score of less than about 4. Claims 3 and 4 have also been amended to delete reference to the selective breeding process by which the claimed rats are obtained, thereby rendering the “product by process” portion of the rejection moot.

The Declaration submitted herewith states that rats having an FST score of 6 or lower do not exist in nature. Therefore, Paré et al. cannot anticipate the claimed invention because Paré et al. does not teach each and every element of the claim, namely WLI rats having an FST score of about 6 or lower. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### Rejection of claims 3, 4, and 56 in view of 35 U.S.C. §102(a)

The Examiner has rejected claims 3, 4, and 56 as being anticipated by Begum, et al. (1998, Am. J. Physiol., 275:C42-49). In the Examiner’s view, Begum et al. teach WKY rats as discussed above for Paré, and also teach obtaining cells from the WKY rat. Further, the Examiner states that the patentability of a “product-by-process” claim is determined by the novelty of the claimed product itself, and it is the Examiner’s view that Applicants’ claims do not recite a novel product. Applicants respectfully disagree with the Examiner’s analysis for the following reasons.

The test for anticipation under 35 U.S.C. §102 is set forth above. Applicants have amended claims 3 and 56 such that the claims are now drawn to (1) a rat having an FST score of less than about 6, and (2) an isolated cell therefrom. Applicants have amended claim 4 to recite a rat having an FST score of less than about 4. Claims 3, 4, and 56 have also been amended to delete reference to the selective breeding process by which the claimed rats, and

isolated cells therefrom, are obtained, thereby rendering the "product by process" portion of the rejection moot.

The Declaration submitted herewith states that rats having an FST score of 6 or lower do not exist in nature. In view of this statement, Begum et al. does not anticipate the claimed invention because Begum et al. does not teach each and every element of the claim, namely WLI rats having an FST score of about 6 or lower. In addition, Begum et al. does not anticipate an isolated cell from a WLI rat having an FST score of about 6 or lower because Begum et al. does not teach a WLI rat having an FST score of about 6 or lower. Applicants respectfully request reconsideration and withdrawal of the rejection.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that claims 3, 4, and 56 are in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,

**EVA REDEI, ET AL.**

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(Date)

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